

**REMARKS**

1. The Examiner acknowledges that claim 124, which was added in the Amendment and Response filed November 6, 2006, is directed to the elected invention.

2-5. Claims 94 and 123 are withdrawn from further consideration as being drawn to a non-elected species of invention. Claims 75, 84-91, 93, 95-106, and 124 are currently under prosecution.

Applicant has canceled claim 125 without prejudice. Applicant has amended claims 75, 87, 90, 97, 98, 99, 100, and 103 and the claim amendments are supported throughout the specification. Claims 75, 87, 90, 97, and 103 are amended to correct form. Amendments to claims 98 and 99 find support at lines 21-30 on page 3 of the specification, for example. Claim 100 as amended is supported in the specification and in the claims as originally filed. The claim amendments introduce no new matter. Applicant reserves the right to pursue subject matter as originally claimed in the present or future applications.

Applicant notes that the previous amendment mailed on February 16, 2007 was not entered. Applicant respectfully requests entry of this amendment and reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action mailed December 19, 2006.

**Priority**

6. The Examiner maintains that claims 86, 87, 98, and 99 do not properly benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents cited, since these claims stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description and a sufficiently enabling disclosure. The Examiner further maintains that with particular regard to claims 86 and 87, even if issues related to the insufficiency of the disclosure under 35 U.S.C. § 112, first paragraph, were resolved, the prior filed applications allegedly do not describe the practice of the claimed invention of claims 86 and 87. The Examiner disagrees with Applicant's assertion that the skilled artisan would have understood that a stool sample includes both excreted stool and stool

removed from the inner wall and/or lumen of the intestinal tract. Accordingly, the Examiner has deemed the effective filing date of claims 86, 87, 98, and 99 as the filing date of the instant application: August 26, 2003. Applicant respectfully disagrees.

The parent applications (Serial Nos. 10/274,177 and 10/229,345) as filed are fully compliant with the requirements of the first paragraph of 35 U.S.C. § 112, and accordingly amended claims 98 and 99 benefit from the filing dates of the earlier filed applications. With regard to claims 86 and 87, the parent applications both disclose using a biological sample such as a stool sample; U.S. Application No. 10/274,177 describes detecting markers in stool samples (see, for example, paragraphs 0004, 0014, 0112, 0114, 0144, 0150, and claim 17), and U.S. Application No. 10/229,345 similarly describes using stool samples. Therefore amended claim 87, which depends from claim 75 and recites a biological sample that is a stool sample, is entitled to benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents.

Although Applicant disagrees with the Examiner's assertions regarding priority, Applicant nonetheless notes the effective priority date of claim 86. This acknowledgement should not be construed as acquiescence to the Examiner's remarks. With regard to claims 98 and 99, Applicants respectfully request the Examiner reconsider the effective priority date in view of the comments below.

#### **Grounds of Objection and Rejection Withdrawn**

7. Applicant acknowledges with appreciation the withdrawal of the rejections under 35 U.S.C. §§ 102(a) and 102(e).

#### **Grounds of Objection and Rejection Maintained**

8. The Examiner maintains the objection of claims 75, 84-91, 93, and 95-106 because the claims are directed in the alternative to the subject matter of a non-elected invention. Applicants respectfully remind the Examiner that these claims should be rejoined upon a finding of allowable subject matter as the Examiner indicated in the Office Action dated July 6, 2006. Specifically the Examiner stated:

Claims 75, 84-91, and 95-106 are objected to because the claims are directed in the alternative to the subject matter of a non-elected invention. Nonetheless, because the claimed subject matter may be rejoined later during prosecution, Applicant need not remedy this issue at the present time."

In addition, Applicant reiterates the arguments already made of record and respectfully traverses the sequence election requirement. A simultaneous search of the polypeptides of SEQ ID NOs: 3 and 21 would not impose serious burden on the Examiner. The amino acid sequence set forth in SEQ ID NO: 21 is a portion of the sequence set forth in SEQ ID NO: 3 and therefore a search of SEQ ID NO: 3 would necessarily encompass a search of SEQ ID NO: 21. Applicant respectfully requests the Examiner to withdraw the species election requirement (at least with respect to SEQ ID NOs: 3 and 21) and rejoin claims 94 and 123 with the elected invention.

Applicants further note that claim 75 is a generic claim linking elected and non-elected species sequences. Pursuant to MPEP 809.04, "[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim." Thus, restrictions imposed on species encompassed by generic claims must be withdrawn upon indication of an allowable generic claim (MPEP 809). In other words, upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141 (MPEP 809.02(a)).

Applicant believes that claims 93 and 94 should also be capable of rejoinder as the claims are still directed to "detection of a polypeptide" and not detection of a nucleic acid. Applicant respectfully requests that the Examiner consider the claims as directed in the alternative to the non-elected subject matter.

### **Claim Rejections – 35 U.S.C. § 112**

9. The Examiner maintains the rejection of claims 99, 100, and 103 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) With regard to claim 99, the Examiner contends that the metes and bounds of “the subject’s historical baseline” are not clear. In an effort to expedite prosecution, Applicant has amended claim 99 as suggested by the Examiner thus rendering this rejection moot.

(b) Claims 100 and 103 stand rejected as allegedly being indefinite. Claim 100 stands rejected because, according to the Examiner, it is not clear why the presence of the polypeptide indicates that the subject is likely to harbor a colon adenoma or a colon cancer as opposed to some other type of colon neoplasm. The Examiner suggests amending claim 100 to recite “wherein said colon neoplasm is a colon adenoma or a colon cancer”. The claim is hereby amended according to the Examiner’s suggestion in order to more clearly point out the claimed invention. This amendment does not change the scope of the claimed invention.

The Examiner has similarly rejected claim 103 and argues that it is not clear whether or not the outcome of claim 103 requires some other active step that is not recited. The Examiner further states that because claim 103 depends from claim 75, which is drawn to a process for determining whether a subject is likely to have a colon neoplasm, it is unclear why the invention of claim 103 would be practiced using a biological sample acquired from a subject known to have colon neoplasia. Applicant disagrees with the Examiner's position but has nonetheless amended claim 103 for greater clarity. Claim 103 as amended specifies that the subject was previously cured of colon cancer, wherein the presence of said at least one secreted ColoUp2 polypeptide indicates that the subject is likely to have a relapse of colon cancer.

Applicant believes the redrafted claims obviate the claim rejections and respectfully requests reconsideration and withdrawal of these rejections.

10. The Examiner maintains the rejection of claims 98 and 99 under 35 U.S.C. § 112, first paragraph, written description. The Examiner maintains that the claims are directed to particular values and that the values of a “predetermined standard” and a “subject’s historical baseline” are not sufficiently described. Although Applicant disagrees with the Examiner, Applicant has considered the Examiner’s suggested claim amendment on page 9 of the Office Action and has amended claims 98 and 99. Claim 98 as amended recites active steps of determining amounts of polypeptides and comparing the amounts. Claim 99 has also been amended to obviate this ground of the rejection.

The claims fully satisfy the written description requirement, as the claim terms and recited steps are fully described throughout the specification (see, e.g., lines 23-27 on page 3 and lines 13-17 on page 20). Accordingly, Applicant requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, written description.

11. The Examiner also maintains the rejection of claims 98 and 99 under 35 U.S.C. § 112, first paragraph, enablement for reasons of record. Applicant traverses. Nonetheless, and solely to expedite prosecution, Applicant has amended claims 98 and 99 as described above. In view of these claim amendments, Applicant believes the claimed invention is enabled and requests reconsideration and withdrawal of the rejection.

### **New Ground of Objection**

12. The Examiner objects to claim 124 insofar as it is directed to the subject matter of the non-elected species of invention.

Applicant respectfully disagree. Claim 124 is directed to SEQ ID NO: 3 which is the elected sequence. Clarification is respectfully requested.

### **Advisory Action mailed March 20, 2007**

13. The Advisory Action asserts that claim 125 is directed to an invention that is patentably distinct from the elected invention (i.e., the invention of Group I, claims 75-107).

Solely to expedite prosecution of the application, Applicant has canceled claim 125 without prejudice; the subject matter has been included in amended claim 103.

14. The Advisory Action asserts that claim 75 includes non-elected species by reciting "a secreted polypeptides produced by the expression of a nucleic acid having the sequence of SEQ ID NO: 5," but the only species described with any particularity is the polypeptide of SEQ ID NO: 3. The Examiner further asserts that entry of the amendment would raise new issues under 35 U.S.C. § 112, both in terms of the written description and enablement provisions set forth thereunder.

Applicant respectfully disagrees. Contrary to the Examiner's assertion, the specification teaches at least two species sequences, SEQ ID NO: 3 and SEQ ID NO: 21 (e.g., lines 13-21 on page 8, and Example 13 on page 57). Applicant further points out that the specification sufficiently teaches association of colon neoplasm with the presence of either SEQ ID NO: 3 or 21 and also provides working examples (e.g., Examples 1, 5, 6, 7, 10, 11, 12, and 13). Thus, all pending claims as amended satisfy both written description and enablement requirements. Applicant requests the Examiner to withdraw the sequence election requirement at least with respect to SEQ ID NOs: 3 and 21 which are linked by independent claim 75.

### **CONCLUSION**

In view of the amendments and at least the forgoing remarks, Applicant believes the pending claims are in condition for allowance and requests the Examiner reconsider the pending claims. If any additional fees are due, please charge our Deposit Account No. 18-1945, under Order No. CWRU-P03-003 from which the undersigned is authorized to draw.

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Respectfully submitted,

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